UNITED STATES PATENT APPLICATION

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FOR: SAFETY SHIELDING NEEDLE ASSEMBLY WITH PASSIVE SHIELDING

RELATED APPLICATIONS

This application claims priority on U.S. Provisional Patent Appl. No. 60/463,384 filed April 16, 2003.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to a safety needle assembly with a telescoping shield that is activated during a standard sequence of operation of a medical procedure and, more particularly, relates to a needle and hub assembly having a telescoping shield that is activated when a sampling tube is removed from a needle holder.

2. Description of the Related Art

[0002] An evacuated collection tube, needle cannula (generally a double ended needle cannula) and needle holder are commonly used by a doctor, phlebotomist or nurse to draw a sample of body fluid from a patient in a hospital or doctor's office for diagnostic testing. During the use of such a collection needle assembly, the distal end of the needle cannula

in the needle holder is inserted into the vein of the patient. The evacuated collection tube is then inserted into the proximal end of the needle holder until a needle (the proximal end of a double ended needle cannula) within the needle holder pierces a closure on the end of the tube. The vacuum in the tube then draws a body fluid sample from the patient through the needle cannula and into the tube. After the collection process is complete the needle cannula is removed from the vein and disposed of.

[0003] Because of the great concern that users of such needles may be contaminated with the blood of a patient by accidental sticks from the contaminated needle, it is preferable to cover the contaminated needle as soon as it is removed from the vein. For this reason, many developments have been made to provide means for covering the contaminated needle once it is removed from the patient. These devices usually involve some sort of shield arrangement that moves in place over the contaminated needle once it has been removed from the patient. However, these shield arrangements have required the use of one or two hands to perform the operation of moving the shield over the contaminated needle, which is a hindrance to the user.

[0004] Alternatively, needles with internal or external blunting cannulas have been used that extend from the needle to blunt the distal end. However, these devices require an additional manual operation to drive the blunting cannula over or out of the needle upon completion of blood drawing to protect the user from the sharp end of the needle and also allow the user to draw blood without triggering the safety device. Such devices also require the internal diameter of the needle to be decreased, which may affect blood flow or require the external diameter of the needle to be enlarged and may cause unnecessary discomfort to the patient.

[0005] Other needles have shields that are activated during the venipuncture operation when the shield comes in contact with the skin. Using the skin to activate the device is not desirable since the device may not activate if the needle does not penetrate sufficiently or may cause the shield to inadvertently lock when probing for the vein. Such devices may also require excessive penetration into some patients to cause the triggering means to activate the device, which will cause a phlebotomist to unnecessarily have to change their standard method or procedure.

[0006] U.S. Patent Nos. 5,718,239 and 5,893,845, which are incorporated herein by reference, provide safety needle assemblies incorporating a telescoping shield that extends over the distal end of the needle cannula when released by an actuator that is triggered during a standard sequence of operation of a medical procedure. In particular, when the closure or stopper on the collection tube compresses a rubber multiple sample sleeve on the proximal end of the needle cannula, an actuator is triggered by the closure and/or sleeve to cause the telescoping shield to extend to contact the skin of a patient. Then, when the needle end of the cannula is removed from the patient, the telescoping shield continues to extend to a fully extended and locked position over the distal end of the needle cannula, thereby rendering the needle assembly safe and preventing needle stick injuries.

[0007] Although providing significant improvements over the prior art systems, the system of the '239 and '845 patents involving deployment of the telescoping sleeve upon tube insertion can be a distraction to the user, in the event they must probe for the vein after shield is activated. There is a need, therefore, for a safety shielding needle mechanism that does not require manipulation beyond that which is familiar to medical technicians with the use of conventional blood collection needles and which is deployed following the withdrawal of the tube from the needle holder.

[0008] An object of the present invention is to provide a needle shield that is automatically activated during the normal procedure used during blood collection. It is a further object of the present invention to provide a needle assembly shielding mechanism that is activated upon insertion of an evacuated tube into the needle holder and deployed upon withdrawal of the tube from the needle holder.

SUMMARY OF THE INVENTION

[0009] The above problems with the prior art are addressed with a passively shielded needle assembly according to the present invention. The present invention includes a needle cannula, such as a double ended needle cannula, having a proximal end and a distal end with a hub mounted to the needle cannula at a location spaced from the distal end. The invention includes a telescoping shield slidably mounted on the hub and moveable

between a fully retracted position and a fully extended position encapsulating the distal end of the needle cannula. A first biasing member, such as a spring, may be mounted on the hub and bias the telescoping shield towards the fully extended position. The hub may include a releasable lock for initially holding the telescoping shield in the fully retracted position. An actuator may be moveably mounted on the hub for releasing the lock, wherein the actuator is activated by pressure applied during a standard sequence of operation of a medical device, such as insertion of an evacuated tube into a needle holder that is coupled to the hub. Significantly, the invention includes a retaining member moveably mounted on the hub and releasably engageable with the telescoping shield, wherein the retaining member holds the telescoping shield from moving toward the fully extended position when engaged therewith. The telescoping shield will move toward the fully extended position when the actuator has released the lock and the retaining member is disengaged from the telescoping shield, such as upon removal of an evacuated tube from the needle holder.

[0010] In one embodiment of the invention, the actuator may include at least one actuating arm slidably mounted on the hub for releasing the lock. Further, the lock may include at least one locking recess and the telescoping shield may include a corresponding locking lug, wherein each locking recess is engageable with a corresponding locking lug, and wherein the actuating arm disengages each locking lug from the corresponding locking recess to release the lock. The retaining member may include at least one retaining arm slidably mounted on the hub, wherein the retaining member engages at least one locking lug after the actuating arm has disengaged the locking lug from the locking recess.

[0011] The invention may include a biasing member biasing the retaining member away from engagement with the telescoping shield. Further, this biasing member may be positioned to be prevented from moving the retaining member away from engagement with the telescoping shield for a period of time following when the actuator is activated by pressure applied during the standard sequence of operation of the medical device. For example, the biasing member may be prevented from moving the retaining member out of engagement with the telescoping sleeve until the evacuated tube is removed from the needle holder.

[0012] The invention may further include a second lock, such as a cannula lock or a locking engagement between the telescoping shield and the hub, for securing the telescoping shield in the fully extended position. The invention may further include a manual shield activation to allow the operator to manually deploy the shield if desired and supplement the automatic passive deployment features.

[0013] The present invention provides a method of passively shielding a needle assembly including the steps of: providing and mounting a needle holder on the hub; inserting an evacuated tube onto the needle holder; engaging the telescoping shield with the retaining member upon insertion of the evacuated tube to prevent the telescoping shield from moving to a needle cannula encapsulating position; removing the evacuated tube from the needle holder; disengaging the retaining member from the telescoping shield with the removal of the evacuated tube; and moving the telescoping shield toward the needle cannula encapsulating position with the removal of the evacuated tube from the needle holder.

[0014] These and other objects and further advantages of the invention will be more readily understood upon consideration of the following detailed description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 is a perspective view of a needle assembly according to the present invention;

[0016] FIG. 2 is an exploded perspective view of the needle assembly shown in FIG. 1;

[0017] FIG. 3 is a perspective view of the needle and holder assembly shown in FIG. 2 with a packaging shield covering the needle cannula before use;

[0018] FIG. 4 is a perspective view of the needle assembly of FIG. 1 with a needle shield covering the needle cannula after use;

[0019] FIG. 5 is an exploded perspective view of the cannula, a hub sub-assembly, housing and holder sub-assembly;

[0020] FIG. 6 is a partially exploded view of the cannula and the hub sub-assembly and housing;

[0021] FIG. 7 is an enlarged view of a portion of FIG. 6;

[0022] FIG. 8 is an exploded perspective view of a needle assembly with a detached holder according to the present invention;

[0023] FIG. 9 is an exploded perspective view of the needle assembly of FIG. 8 with a non-patient shield detached;

[0024] FIG. 10 is an exploded perspective view of the needle assembly of FIG. 8 with the packaging and non-patient shield detached;

[0025] FIG. 11A is a front view of the housing of the present invention;

[0026] FIG. 11B is a perspective sectional view of the housing of FIG. 11A taken along line 11B, 11C-11B, 11C in FIG. 11A;

[0027] FIG. 11C is a perspective sectional view of the housing of FIG. 11A taken along line 11B, 11C-11B, 11C in FIG. 11A;

[0028] FIG. 12A and 12B are perspective and side elevational views, respectively, of a safety needle shield of the present invention;

[0029] FIG. 12C is a side elevational view of the safety needle shield of FIGS. 12A and 12B with a deflectable member in an unbiased position;

[0030] FIG. 12D is a side elevational view of the safety needle shield of FIGS. 12A and 12B with the deflectable member in a biased position;

[0031] FIG. 13 is an elevational view of the actuator of the present invention;

[0032] FIG. 14 is a perspective view of an actuator of the present invention;

[0033] FIG. 15 is a perspective view of a hub and a portion of a retaining member of the present invention;

[0034] FIG. 16 is a side elevational view of the hub and retaining member of FIG. 15;

[0035] FIG. 17 is a side elevational view of the needle assembly prior to shielding;

[0036] FIG. 18 is a side elevational view of the needle assembly after shielding;

[0037] FIG. 19A is a sectional view of the present invention before actuator safety shield release;

[0038] FIG. 19B is a sectional view of the present invention during actuator safety shield release with engagement of the retaining member;

[0039] FIG. 19C is a sectional view of the present invention after actuator safety shield release and disengagement of the retaining member where the shield is covering the distal

end of the needle cannula;

[0040] FIG. 20A is a perspective sectional view of the present invention before actuator safety shield release;

[0041] FIG. 20B is a perspective sectional view of the present invention during actuator safety shield release during engagement of the retaining member;

[0042] FIG. 20C is a perspective sectional view of the present invention after actuator safety shield release and disengagement of the retaining member where the shield is covering the distal end of the needle cannula;

[0043] FIG. 21 is a perspective view of another embodiment of the present invention;

[0044] FIG. 22 is a perspective view of a holder for use with the embodiment of FIG. 21;

[0045] FIG. 23 is a perspective view of a hub for use with the embodiment of FIG. 21;

[0046] FIG. 24 is a perspective view of an actuator for use with the embodiment of FIG. 21;

[0047] FIG. 25 is a sectional view of the needle assembly shown in FIG. 21;

[0048] FIGS. 26A and 26B are enlarged schematic views illustrating the engagement of the retaining member and the safety shield in the embodiment of FIGS. 19A-19C; and

[0049] FIG. 27 is a perspective schematic view of another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0050] The needle assembly **10** of the present invention is shown in FIGS. 1-7 and 11-20. It will be noted that the term "distal" as used herein refers to the end of the needle assembly that punctures the patient's skin while "proximal" means the end of the needle assembly that punctures an evacuated container. Needle assembly **10** is mounted to a needle holder **12**, as shown in FIGS. 1, 3, and 4. Needle holder **12** has a proximal end **14**, a distal end **16** and a tubular sidewall **18** extending between ends **14** and **16**. Proximal end **14** of needle holder **12** is open and is adapted to receive a blood collection tube **20** as shown in FIGS. 17, 19A-19C, and 20A-20C. FIGS. 20A-20C omit the retaining member for clarity. However, proximal end **14** of holder **12** may have a removable seal or cap **15** for sterility. Proximal end **14** of holder **12** also has a radially aligned finger flange **17** to

facilitate manipulation of holder **12**. Flange **17** is a non-circular to prevent holder **12** from rolling. Flange **17** preferably has a linear edge to provide a clear indication of the top and bottom sides. Distal end **16** of needle holder **12** includes structure to which needle assembly **10** is mounted. In particular, distal end **16** of needle holder **12** may be formed with non-threaded mounting means, such that needle holder **12** is substantially fixed to needle assembly **10** after assembly. The non-threaded mounting means comprises a combination of external rings **81** and keyways to secure needle assembly **10** axially and circumferentially. It is preferred that needle assembly **10** is mounted to needle holder **12** by the manufacturer so that the device is ready for fast and convenient use. Most importantly, pre-assembled needle assemblies **10** and needle holders **12** ensure that the proximal point of the needle is enclosed within holder **12** before, during, and after blood collection. Alternately, however, the distal end of the needle holder may be formed with an internal array of threads that are engageable by external threads on the needle assembly.

[0051] Needle assembly **10** ideally is packaged in a blister package having a thermoformed blister and top web. The top web is comprised of a material that may be permeable to gas such as ethylene oxide gas. Optionally, the proximal end **14** of the holder **12** can be covered with a paper-like membrane that is thermally or adhesively sealed onto the proximal end **14** of the holder. Examples of materials used for a paper-like membrane are Tyvek® manufactured by DuPont, and examples of materials to be used for a thermoformed blister package include glycol modified polyethylene terephthalate (PETG), polyethylene terephthalate (PET), high-density polyethylene, polypropylene, polycarbonate, nylon, and K-resin. In the configuration with a paper-like membrane covering the open proximal end **14** of holder **12**, a thermoformed blister and top web would not be required, and the entire assembly can be sterilized by ethylene oxide gas or cobalt 60 irradiation.

[0052] Needle assembly **10** includes a needle cannula **22**, a needle hub **24**, a packaging shield **26**, a safety shield **28**, a sleeve **39**, a housing **80**, an actuator **30**, a releasable retaining member **35**, and a spring **32**. In other embodiments, a portion of the needle assembly (e.g., the housing **80**) can be integral or unitary with the needle holder or hub to

reduce assembly steps by the manufacturer and the user.

[0053] Needle cannula **22** includes a pointed proximal end **34**, as shown in FIGS. 1, 5, and 6, a sharply beveled distal end **36** and a lumen **38** extending therebetween. Proximal end **34** of needle cannula **22** is covered by an elastomeric multiple sample sleeve **39** (shown in FIGS. 2, 9, and 10) that can be pierced by pointed proximal end **34** of needle cannula **22**.

[0054] Needle hub **24** is illustrated in greater detail in FIGS. 15 and 16. Needle hub **24** includes a proximal end **40**, a distal end **42**, and a lumen **38** extending therebetween. Housing attachment means is provided externally of hub **24** to achieve fixed engagement between hub **24** and needle housing **80**. The housing attachment means may include ultrasonic welding, heat staking, solvent bonding, mechanical latches with receiving latch detents, adhesive bonding, friction fit joints, irreversible threads, or any of the like. In the embodiment of FIGS. 5, 6, 7, 15, and 16, the housing attachment means are defined by mechanical latches **86** that extend distally from needle hub **24** for engagement in detents **88** on needle housing **80**. Hub **24** is mounted securely to locations on needle cannula **22** between proximal and distal ends **34** and **36** thereof, and in a specified rotational orientation relative to the bevel at distal end **36** of needle cannula **22**. More particularly, an adhesive well is formed on needle hub **24** and receives adhesive to bond needle cannula **22** to hub **24**. Alternately, needle hub **24** and needle housing **80** may be combined as one molded component. However, it is generally easier to manufacture needle hub **24** and housing **80** as two components. The housing **80** may be considered an extension of or part of the hub **24**, particularly in connection with the retaining member **35**.

[0055] Needle housing **80** is illustrated in greater detail in FIGS. 11A-11C. Needle housing **80** includes a proximal end **82**, a distal end **84**, and a tubular wall **44** extending between ends **82** and **84**. As shown in FIGS. 11A-11C, tubular wall **44** is of generally circular or elliptical cross-section. Alternately, tubular wall **44** may have a non-circular cross-section or rectangular cross-section. The specific cross-sectional shape is not critical, and shapes other than those shown herein are contemplated. Housing **80** preferably is formed from a transparent or translucent material to permit user observation of safety shield **28**. Thus, the medical practitioner can observe movement of safety shield

28, as explained below, to provide a visual indication that proper shielding is taking place. Additionally, proximal end **82** of housing **80** may have one of many optional means for attachment to a needle holder **12**, such as a threaded connection, interference fit, adhesive bonding, solvent bonding, ultrasonic welding, heat staking, snap fit, or any other means. More specifically, the housing may have external threads and may be mounted to internal threads of the distal end of the needle holder. Alternately, housing **80** has non-threaded mounting means to engage holder **12** in an interlocking manner. External rings **81** are illustrated in FIGS. 5-7 and define one preferred non-threaded mounting means that provide sufficient friction or interlocking forces to resist housing **80** from unintentionally releasing from holder **12** during puncturing of septum **21** by proximal end **34** of needle cannula **22**. In the illustrated embodiment, hub **24** is mounted indirectly to the holder **12** through needle housing **80**. Housing **80** preferably is non-rotatably mounted to holder **12** to ensure that the bevel at distal end of needle cannula **22** faces up relative to the bottom edge of flange **17** of holder **12**. Distal end **84** of needle housing **80** is characterized by diametrically opposed V-shaped notches **85** as shown in FIG. 11B. Notches **85** cooperate with corresponding structure on packaging shield **26**.

[0056] Housing **80** has a length such that distal end **84** of housing **80** is spaced proximally from distal end **36** of needle cannula **22** sufficiently to enable convenient use of needle cannula **22**. Portions of tubular wall **44** from distal end **84** toward proximal end **82** of hub **24** are spaced outwardly from needle cannula **22** for permitting telescoped movement of safety shield **28** between needle cannula **22** and housing **80**, as explained further below. Additionally, as shown in FIGS. 1, 3, and 4, tubular sidewall **44** of housing **80** is provided with external surface configurations or grips **46** include elongate recesses or flats having small bumps thereon. However, other surface configurations may be employed, such as a plurality of ridges or grooves, or concave detents shaped to conform to a user's fingers. Grips **46** preferably are orthogonal to the bottom edge of finger flange **17** of holder **12**.

[0057] Housing **80** has internal features to restrict movement of safety shield **28** relative to housing **80**. Tubular wall **44** of housing **80** is formed with a first proximal facing stop surface **48**. As shown in FIG. 11B, housing **80** further includes an axially extending latch channel **52** formed on an interior surface of tubular wall **44**. Latch channel **52** extends

from the first proximal facing stop surface **48** shown in FIG. 11C to a location substantially adjacent distal end **84** of housing **80** as shown in FIG. 11B. A distal detent **47** is located near the distal end of tubular wall **44** of housing **80**, as shown, and is at the distal end of latch channel **52**. Distal detent **47** has a distally facing stop surface **54**. Distal detent **47** and distally facing stop surface **54** are dimensioned to receive a latch **68** on safety shield **28**, as explained below. Tubular wall **44** further includes a stop channel **50** extending distally and ending with a second proximally facing stop surface **58** near distal end **82** of housing **80** as shown in FIG. 11C.

[0058] Distal end **36** of needle cannula **22** is used to pierce the patient's skin and must be kept very sharp. Thus, a packaging shield **26**, as shown in FIGS. 1-3 and 8-10, is used to enclose the distal end **36** of needle cannula **22**. The packaging shield **26** preferably is formed with two opposing relatively flat walls **19** to facilitate easy handling by the phlebotomist who is likely to be wearing gloves that may even be wet with alcohol prep solution. In the embodiment shown, the open end of the packaging shield **26** fits partially over the distal end **84** of housing **80**. The packaging shield **26** and housing **80** are dimensioned so that there is an interference fit that desirably provides a sterile barrier between the packaging shield **26** and housing **80** in those embodiments that do not employ blister packaging. In those embodiments, the interference fit between packaging shield **26** and housing **80** may make separation of packaging shield **26** difficult. Accordingly, for those embodiments, packaging shield **26** is provided with a pair of diametrically opposed ribs (not shown) on the interior surface. The ribs terminate at a V-shaped point or an arcuate end facing toward the open end of packaging shield **26**. The ends of the ribs are disposed, dimensioned, and configured to mate with the V-shaped notches **85** at distal end **84** of housing **80**. The engagement of the ends of the rib with V-shaped notches **85** develops ramping forces in response to twisting of packaging shield **26**. Thus, the rotational movement applied to packaging shield **26** generates a corresponding axial movement of packaging shield **26** relative to housing **80**, and hence facilitates separation of packing shield **26**. Additionally, a tamper-evidence indicator may be placed between the packaging shield **26** and the housing **80** to provide indication of prior usage.

[0059] Safety shield **28**, as shown in FIGS. 12A-12D, includes a proximal end **60**, a distal

end **62**, and a substantially tubular sidewall **64** extending between the ends. Tubular sidewall **64** of safety shield **28** preferably is imprinted with indicia at a location aligned with the bevel-up side of needle cannula **22**. This is the portion of tubular sidewall **64** that will be the most visible to the medical practitioner. The existence of indicia on this portion of tubular sidewall **64** provides a physical indication to the medical practitioner that shielding is taking place. The indicia should be in a form that will provide evidence of movement. For example, a plurality of intermittent markings or a marking that changes its dimensions along its length would be most beneficial. Safety shield **28** initially is retained releasably in a proximal position with at least a major portion of safety shield **28** disposed in the space between needle cannula **22** and tubular wall **44** of housing **80**. In this proximal position, proximal end **60** of safety shield **28** is substantially adjacent first proximally facing stop surface **48** of housing **80**. Additionally, as shown in FIG. 1, distal end **62** of safety shield **28** is flush with or projects only slightly from distal end **84** of housing **80** when safety shield **28** is in its proximal position. Safety shield **28** can be released from its proximal position and is movable to a distal position that is shown in FIGS. 4, 18, 19C, and 20C. When moved into its distal position, safety shield **28** completely covers portions of needle cannula **22** between needle hub **24** and distal end **36** of needle cannula **22**.

[0060] As shown in FIGS. 12B-12D, safety shield **28** has a hinged deflectable member **66** that is cantilevered toward proximal end **60**. Deflectable member **66** is deflectable outwardly or in a transverse direction. A locking lug or latch **68** is formed on deflectable member **66** near proximal end **60** of safety shield **28** and enters latch channel **52** when deflectable member **66** is deflected outwardly. Hinged deflectable member **66** further includes a cam surface **70** at the extreme proximal end thereof. Cam surface **70** is aligned at an acute angle to a radial plane passing through needle assembly **10**. Axially aligned distally directed forces on cam surface **70** will generate a transverse deflection of deflectable member **66** so that latch **68** enters into latch channel **52**. Latch **68** further includes a distal facing locking face **72**, and a proximally facing locking face **73**. Both locking faces **72** and **73** are aligned substantially perpendicular to the axis of needle assembly **10**. FIG. 12C shows deflectable member **66** in its non-deflected state and FIG.

12D shows deflectable member **66** in its deflected state. Distal movement of actuator **30** moves deflectable member **66** from the position shown in FIG. 12C in direction **69** depicted in FIG. 12C to the position shown in FIG. 12D until latch **68** is no longer resisted by first proximally facing stop surface **48** of housing **80** and therefore is free to move distally with respect to the needle cannula **22** under spring energy supplied by spring **32**.

[0061] Safety shield **28** further includes a stop **74** disposed substantially diametrically opposite latch **66**. Stop **74** is in a plane passing through the axis of needle assembly **10** and includes a locking surface **76** facing in the distal direction as shown in FIG. 12A. Stop **74** prevents spring **32** from pushing safety shield **28** past housing **80**.

[0062] Hub **24** is connected to the proximal end **82** of housing **80**. Hub **24** further includes an actuator channel **56** extending substantially parallel to housing **80** as shown in FIGS. 15 and 16. Actuator **30**, as shown in FIGS. 13 and 14, is disposed slidably in actuator channel **56** of hub **24**. Actuator **30** includes a proximal end **78** substantially adjacent to needle cannula **22** that will lie within needle holder **12**. Actuator **30** also includes a distal end **79** that will lie substantially adjacent cam surface **70** of latch **68**. Distal end **80** of actuator **30** is angularly aligned to mate with cam surface **70** of latch **68**, such that distal movement of actuator **30** will generate transverse deflection of deflectable member **66**.

[0063] As shown in FIGS. 13 and 14, actuator **30** has an integrated anti-reset feature or latch **29** that interfaces with hub **24** upon activation of the device. Once a tube **20** is inserted and interfaces with the proximal end **78** of actuator **30**, latch **29** will interface with the hub channel **56** thus deforming latch **29** temporarily inward thereby permitting latch **29** to advance into latch recess **23**. Once latch **29** is within latch recess **23**, latch **29** will return resiliently towards an undeflected position so that actuator **30** is prevented from moving back to a proximal position that would allow safety shield **28** to be completely reset to its original position.

[0064] A spring **32** surrounds portions of needle cannula **22** that are surrounded by safety shield **28**. Thus, spring **32** is compressed to retain stored energy when safety shield **28** is in proximal position within tubular wall **44** of housing **80**. Spring **32** then will propel safety shield **28** distally after activation. The proximal end **31** of spring **32** remains in

fixed relation to the holder **12**, hub **24**, and housing **80** while the distal end **33** of spring **32** moves relative to the holder **12**, hub **24**, and housing **80**.

[0065] The force applied by spring **32** to safety shield **28** is essential to proper operation of needle assembly **10**. In particular, spring **32** must exert sufficient force to ensure that safety shield **28** will be propelled sufficiently toward distal end **32** of needle cannula **22** to complete its essential shielding function. A spring force of 0.02-0.20 pounds, and preferably about 0.09 pounds, has been found to meet the objectives of ensuring complete shielding without excessive force. Additionally, a fine lubricating spray may be applied to the sliding parts of safety shield **22**, hub **24**, and/or housing **80** to ensure complete and efficient movement of safety shield **28** and a low spring force.

[0066] Needle assembly **10** is used by attaching proximal end of hub **24** and housing **80** into needle holder **12** such that proximal end **23** of needle cannula **22** and proximal end **78** of actuator **30** lie within needle holder **12**. Packaging shield **26** then is removed from housing **80** to expose pointed distal end **36** of needle cannula **22**. The medical practitioner then manually engages housing **80** at grips **46** and guides distal end **32** of needle cannula **22** into a targeted vein of a patient. Activation of shield **28** is achieved automatically and passively by insertion of blood collection tube **20** into proximal end **14** of needle holder **12**. Sufficient insertion of blood collection tube **12** will cause proximal end **14** of needle cannula **22** to pierce through the elastomeric septum **21** that extends across the open end of blood collection tube **20**, as shown in FIGS. 19A-19C. Distal movement of blood collection tube **20** into needle holder **12** also will cause blood collection tube **20** to engage proximal end **78** of actuator **30**, thereby causing actuator **30** to slide distally through actuator channel **56** of hub **24**. This distal movement of actuator **30** will cause distal end **79** of actuator **30** to engage cam surface **70** of hinged deflectable member **66** of safety shield **28** with sufficient force to pivot deflectable member **66** transversely about hinge **67** sufficiently to disengage locking face **72** of latch **68** from first proximally facing stop surface **48** of housing **80**.

[0067] A further feature of the present invention is the provision of a retaining member **35**, in which the present invention provides for engaging the telescoping shield **28** with the retaining member **35** upon insertion of the evacuated tube **20** in the needle holder **12**,

wherein the retaining member **35** prevents the telescoping shield **28** from moving to a needle cannula encapsulating position with the retaining member **28** engaged.

[0068] In particular, as seen in FIGS. 19A-19C, the retaining member **35** includes at least one retaining arm **97** slidably mounted with respect to the hub **24**. The retaining member **35** extends longitudinally within holder **12** with a first end supported adjacent proximal end **78** of actuator **30**, and an opposed end extending adjacent at least one locking lug or latch **68** of the actuating arm, i.e., deflectable member **66**. The retaining arm **97** of the retaining member **35** engages locking lug or latch **68** after the actuating arm (i.e., deflectable member **66)** has disengaged the latch **68** from its original position as shown in FIG.19B. The retaining member **35** is omitted from the actuation sequence shown in FIGS. 20A-20C for clarity of the actuator operation. Although FIGS, 19A-19C and FIGS. 26A and 26B depict one embodiment of retaining arm **97** for illustrative purposes, other configurations are considered within the scope of the present invention. Retaining arm **97** of retaining member **35** includes a mating surface **91** for engagement between the retaining arm **97** and the latch **68**. Mating surface **91** may include a cam surface, which may assist in the disengagement of the retaining arm **97** from the latch **68** upon withdrawal of the tube **20** from the needle holder **12**. Retaining arm **97** desirably includes a living hinge **93** incorporated into the retaining arm **97**, which cooperates with the structure of the channel formed in the housing **80**, such as shoulder **83** within housing **80**. As used herein, the hub **24** may include a number of separate components such as the housing **80**.

[0069] An important feature of the present invention is that when the retaining arm **97** is engaged with the latch **68**, the telescoping shield **28** is activated (i.e., out of the locked position) and the engagement is sufficient to prevent the spring **32** from advancing the telescoping shield **28**. In other words, the activated telescoping shield **28** will not be deployed until the retaining arm **97** is disengaged from the latch **68** (also referred to as locking lugs).

[0070] The retaining member **35** further includes a biasing member **95**, biasing the retaining arm **97** away from engagement with the latch **68**. The biasing force of biasing member **95** can be exerted from the resiliency of the material forming the retaining

member **35**, or may be present through a separate member such as a leaf spring or a coil spring, or the like. The biasing member **95** is positioned such that the biasing member **95** is biased against its natural bias between a blood collection tube **20** and shoulder **13** extending radially within holder **12** when a blood collection tube **20** is inserted within holder **12** for sampling purposes. As such, the biasing member **95** is prevented from moving the retaining arm **97** away from engagement with the latch **68** while the tube **20** is in the needle holder **12**. With the withdrawal of the tube **20** from the needle holder **12**, the biasing member **95** will disengage the retaining arm **97** from the latch **68**, and the spring **32** will then fully deploy the telescoping shield **28**.

[0071] The activation of the telescoping shield **28** of the needle assembly **10** is triggered by the insertion of an evacuated blood collection tube **20** having a closure such as septum **21** into needle holder **12**, when a top surface of septum **21** compresses multiple sample sleeve **39** after it has been penetrated by proximal end **34** of needle cannula **22**. This action will also serve to actuate the actuator **30** as discussed above, and to engage the retaining member **35** with the telescoping shield **28**.

[0072] Retaining member **35** is designed so as to maintain the telescoping shield **28** in the retracted position even after the telescoping shield **28** has been activated through actuator **30**, so long as a tube is exerting a force against the natural bias of biasing member **95**. Since activation of actuator **30** occurs through insertion of a tube **20** into needle holder **12**, such tube **20** also engages the retaining member **35**, causing biasing member **95** to be pressed against shoulder **13**, and to be stressed against its natural bias. As such, the telescoping shield **28** is free from engagement of the locking assembly holding it in place in the retracted position, but is still retained in the retracted position due to the interaction of mating surface **91** of retaining member **35** and latch **68**. More particularly, once actuator **30** activates the telescoping shield **28**, the retaining member **35** is advanced such that mating surface **91** is longitudinally forced against shoulder **83** of housing **80**. This movement causes the retaining arm **97** to bend through living hinge **93**, such that mating surface **91** is moved into engagement with latch **68**.

[0073] Once the tube **20** is removed from the needle holder **12**, the stress force exerted against biasing member **95** of retaining member **35** is released, thereby allowing biasing

member **95** to return to its natural bias, as shown in FIG. 19C. This action causes retaining member **95** to be moved out of engagement with the latch **68**, thereby permitting telescoping shield **28** to be propelled to the fully extended position due to the bias of spring **32**.

[0074] The biasing force of spring **32** causes telescoping shield **28** to be propelled to the fully extended position should be less than the force needed to disengage retaining member **35** out of engagement with latch **28**. This ensures that the retaining member **35** will be able to retain the telescoping shield in the retracted position until it is disengaged upon removal of tube **20**. The biasing force of biasing member **95** should be sufficiently strong so as to ensure that retaining member **35** is moved out of engagement with latch **68** upon removal of tube **20**. The specific design of retaining arm **97** of retaining member **35** can function to this effect. For example, retaining arm **97** may have inherent flexibility therein so that it can flex outwardly out of engagement from latch **68**. Alternatively, mating surface **91** may be a cammed surface, which further facilitates the ability for retaining arm **97** to move out of engagement, such as through a rotation of retaining member **35** upon removal of tube **20**. Alternatively, the living hinge **93** may act as a flexing portion of retaining arm **97** to permit it to move out of engagement with latch **68** upon force extended through biasing member **95** upon removal of tube **20**.

[0075] The present invention, therefore, permits the user to perform the medical procedure without changing their normal sequence of operation, since no conscience action is needed to activate or otherwise control telescoping shield **28**. It should be understood that telescoping shield **28** is triggered merely by pushing the closure of a tube **20** onto the proximal end **36** of the cannula **22** and/or compressing the multiple needle sleeve **39**. After the actuator **30** has triggered the transported telescoping shield **28**, the retaining member **35** prevents deployment until the retaining member **35** is disengaged from the latch **68**, which occurs automatically upon tube **20** withdrawal from the needle holder **12**. With the disengagement of the retaining member **35** from the latch **68**, the telescoping shield **28** is moved from the retracted position shown in to a partially extended position against the patient (if the needle is still inserted at time of tube withdrawal), and then to the fully encapsulated position upon needle withdrawal.

[0076] Disengagement of latch **68** from first proximally facing stop surface **48** into latch channel **52** and disengagement of the retaining member **35**, causes safety shield **28** to be propelled distally under the action of spring **32**. Latch **68** will be guided in latch channel **52** as safety shield **28** is moved toward distal end **84** of housing **80**. Sufficient distal movement of safety shield **28** will cause latch **68** to engage in distal detent **47** of housing **80**. While in distal detent **47**, latch **68** interferes with distal facing stop surface **54** and prevents safety shield **28** from being unshielded. Additionally, stop **74** on safety shield **28** rides along stop channel **50** until stop **74** engages second proximally facing stop surface **58** thereby preventing safety shield **28** movement in the distal direction after needle point **36** has been shielded. As a result of stop **74** and latch **68**, safety shield **28** is prevented from moving either distally or proximally from this locked position as shown in FIGS. 18, 19C, and 20C.

[0077] The above-described needle assembly is completely passive in that shielding is achieved without any required user activation other than the normal insertion and withdrawal of a fluid collection tube **20** into the open proximal end **14** of holder **12**.

[0078] There may be instances, however, where a user may want direct control over the initiation of shielding, or where a user may want dual control where shielding can be actuated by insertion of a fluid collection tube and/or by direct digital activation by the user. These options can be achieved without a complete redesign of the above-described needle assembly. In particular, an alternate needle assembly is identified generally by the numeral **10a** in FIGS. 12-25. Assembly **10a** includes a needle cannula **22**, a hub **24**, a packing shield **26**, and a housing **80**, all of which are substantially identical to corresponding parts of the first embodiment described and illustrated above. However, assembly **10a** includes a holder **12a** that is slightly different from holder **12** described and illustrated above. Holder **12a** includes a tubular sidewall **18a** that has a proximal end **14a**, a distal end **16a**, and a tubular sidewall **18a**. A notch **17a** extends into tubular sidewall **18a** at distal end **16a**. Additionally, notch **17a** is disposed on a portion of sidewall **18a** that will align with the bevel-up side of needle cannula **22**. Notch **17a** is partly surrounded by an elongate flat or recess **19a** in tubular sidewall **18a** to minimize the projection of an actuator, as explained herein and to provide a visible indication of a

region to be accessed by a user for carrying out a manual actuation of the shielding.

[0079] Needle assembly **10a** further includes an actuator **30a** that differs from actuator **30** described and illustrated above. In particular, actuator **30a** includes an actuating beam **31a** with a distal end **79a** that is structurally and functionally virtually identical to distal end **79** of actuator **30** described above and illustrated in FIGS. 13 and 14. Additionally, actuating beam **31a** includes an anti-reset latch **29a** that is functionally substantially identical to latch **29** of actuator **30**. Actuator **30a** further includes a mounting collar **77a** that is disposed and configured to mount slidably over proximal portions of hub **24** and further includes a proximal end **78b** that is identical to proximal end **78** of actuator **30**. Additionally, mounting collar **77a** is dimensioned for slidable disposition within holder **12a**. Actuator **30a** further includes an arm **90a** that projects distally from collar **77a**. Arm **90a** is dimensioned for slidable insertion in notch **17a** of holder **12a**, and terminates at an actuating button **92a**.

[0080] Needle assembly **10a** is assembled substantially as needle assembly **10** described and illustrated above. However, collar **77a** of actuator **30a** is slidably disposed over and around proximal portions of hub **24a**. The subassembly of needle cannula **22**, hub **24**, packing shield **26**, holder **80**, and actuator **30a** can be mounted in holder **12a** substantially as described above. However, arm **90a** will project slidably through notch **17a** such that actuating button **92a** is slidably disposed on the outer circumferential surface of holder **80a**.

[0081] Needle assembly **10a** is used substantially in the conventional manner as explained above. However, safety shield **28** may also be actuated by digital pressure exerted by a thumb or forefinger of the user on actuator button **92a**. In particular, if the user urges actuator button **92a** distally along outer surface of holder **80**, a sufficient distance for distal end **79a** of actuator **30a** to actuate safety shield **28**, the safety shield will be actuated. Actuator **30a** permits shielding to be completed either by insertion of an evacuated tube into holder **80** or by digital pressure on actuator button **92b**. The retaining member **35** further includes a biasing member **95**, which performs the same function as described in the previous embodiments.

[0082] The internal disposition of safety shield **28** within the housing in any of these

embodiments provides several significant advantages. In particular, a medical practitioner employing needle assembly **10** can hold needle assembly **10** much closer to distal end **32** of needle cannula **22**. This distal location for gripping needle assembly **10** provides better balance and feel for the medical practitioner and facilitates alignment and aiming of needle assembly **10**.

[0083] Alternately to the embodiments described above, the needle assembly can be made in a detachable holder or hard pack assembly **100** configuration using all the components of the needle assembly described above with the addition of a non-patient needle shield **90** for enclosing proximal end **34** of needle cannula **22** shown in FIGS. 8-10. Non-patient needle shield **90** is reversibly detachable to one or both of needle housing **80** and hub **24**. The user removes non-patient needle shield **90** from hardpack assembly **100** and attaches holder **12** to the proximal end of housing **80** prior to use. Once holder **12** is attached to housing **80**, the user can remove packaging shield **26** and use the needle device in a similar manner to the needle assembly embodiment described herein.

[0084] FIG. 27 is a perspective view of a passively shielded needle assembly **100** according to another embodiment of the present invention in a starting retracted position. Assembly **100** includes a needle cannula **102** mounted in a hub **105** having a telescoping shield **103** mounted thereon for movement from a starting retracted position to an activated non-deployed position through a venipuncture partially extended position to a fully extended and locked position covering a distal end **106** of needle cannula **102**. A proximal end **107** of needle cannula **102** is encompassed by an elastomeric or rubber multiple sample sleeve **108** that is attached to a distal end of hub **105** to seal proximal end **107** and prevent fluid from flowing through cannula **102**. The details of the structure of the hub **105**, an actuator **104**, and the telescoping shield **103** are described in detail in U.S. Patent Nos. 5,718,239 and 5,893,845 and are incorporated herein by reference. A further key feature of the present invention is the provision of a retaining member **35a**, in which the present invention provides for engaging the telescoping shield **103** with the retaining member **35a** upon insertion of the evacuated tube in the needle holder **120**, wherein the retaining member **35a** prevents the telescoping shield **103** from moving to a needle cannula encapsulating position with the retaining member **35a** engaged. The retaining

member **35a** is essentially the same as retaining member **35** discussed above.

[0085] The retaining member **35a** includes at least one retaining arm **97a** slidably mounted on the hub **105**. The retaining arm **97a** of the retaining member **35a** engages at least one locking lug **111** after the actuating arm **115** has disengaged the locking lug **111** from the locking recess. The important feature of the present invention is that when the retaining arm **97a** is engaged with the locking lugs **111**, the telescoping shield **108** is activated (i.e. out of the locked position) and the engagement is sufficient to prevent the spring **119** from advancing the telescoping shield **103**. In other words, the activated telescoping shield **103** will not be deployed until the retaining arm **97a** is disengaged from the locking lugs **111**. The retaining member **35a** further includes a biasing member **95a** biasing the retaining arm **97a** away from engagement with the locking lug **111**. The biasing member **95a** can be formed from the resiliency material forming the retaining member **35a**, or may be a separate member such as a leaf spring or a coil spring, or the like. The biasing member **95a** is positioned such that the biasing member **95a** is prevented from moving the retaining arm **97a** away from engagement with the locking lug **111** while the tube is in the needle holder **120**. With the withdrawal of the tube from the needle holder **120**, the biasing member will disengage the retaining arm **97a** from the locking lug **111** and the spring will then deploy the telescoping shield **103**.

[0086] The above described needle assembly **100**, with its telescoping shield **103**, may be used by a phlebotomist in the following manner and method. After a user has removed needle assembly **100** from its sterile package, it is snap mounted or screw mounted onto distal end of needle holder **120**. The user then prepares a venipuncture site on the patient's skin and applies a tourniquet prior to venipuncture. Venipuncture is then performed by inserting distal end **106** of needle cannula **102** into patient's skin and into a vein. When distal end **106** has been properly inserted and evacuated blood collection tube with its closure is inserted into open end **122** of needle holder **120**, closure is then punctured by proximal end **107** of needle cannula **102**. When puncture of the closure has occurred sufficiently to contact and move actuator **104** in a distal direction, cam face **110** on arm **115** of actuator **104** meets with mating surface **116** on lug **111** of shield **103** to cause shield **103** to rotate and to activate transportation of shield **103**. Simultaneous with the

movement of the actuator **104,** the retaining member **35a** will be advanced by the closure to engage retaining arm **97a** with the lug **111** preventing movement of the telescoping shield **103** in the distal direction toward the venipuncture site. Upon removal of the tube, the biasing member **95a** will disengage the retaining member **35a** from the telescoping shield **103** allowing further deployment of the shield **103**.

[0087] In addition to activating telescoping shield **103**, when proximal end **107** enters into evacuated tube body fluid, flows through cannula **102** into the evacuated tube and when sufficient body fluid has been received, the user can remove evacuated tube from tube holder **120** which will deploy the telescoping shield **103** as described above. The user can continue drawing body fluid with additional evacuated blood collection tubes with the telescoping shield in a partially extended position adjacent the patient's skin. When the evacuated blood collection tube is removed from needle holder **120**, multiple sample sleeve **108** returns to its original position to close and seal distal end **107** of cannula **102** and stops the flow of body fluid through cannula **102**. When no more body fluid is desired to be collected, needle cannula **102** is withdrawn from the patient's vein and skin permitting shield **103** to further extend to the fully extended, and preferably locked position where distal end of shield **103** extends beyond and sufficiently shields distal end **106** of needle cannula **102**.

[0088] In the foregoing discussion, it is to be understood that the above-described embodiments of the present invention are merely exemplary. For example, the distal locking pocket can alternatively be located linearly in the channel at the distal end of the needle hub to alleviate the need for rotation by the torsion spring. In addition, of course, the present invention is not limited to activation by a blood collection tube. Other suitable variations, modifications, and combinations of the above described features could be made to, or used in these embodiments and still remain within the scope of the present invention. It is intended that the invention be construed as including all such modifications and alterations. The scope of the present invention is intended to be defined by the appended claims and all equivalents thereof.